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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. END 727 DIVI/GSG 5468 07/02/2003 Randy R. Stephens 10/612,785 **EXAMINER** 27777 06/22/2004 7590 PHILIP S. JOHNSON MARMOR II, CHARLES ALAN JOHNSON & JOHNSON ART UNIT PAPER NUMBER ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 3736

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. 10812,785 STEPHENS ET AL Examiner Charles A. Marmor, II 3736  Period for Reply  A SHORTENEO STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILUNG DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  A SHORTENEO STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILUNG DATE of THIS COMMUNICATION.  - Emissions of time may be an available under the provisions of 37 CPR 1.136(a). In one event, however, may a reply be freingly liked before the control gate of this communication and the principle of the state of the communication.  - If the particle reply reported shore is less than thin (30) days, a reply and event principle of the communication.  - If the particle reply reported shore is less than thin (30) days, a reply and event principle of the communication.  - If the particle reply reported shore is less than thin (30) days, a reply and event principle of the provision of the communication.  - If the particle reply reported shore is less than the months after the mailing date of this communication, even if timely filed. Independent provision and the communication, even if timely filed. Independent provision and the communication, even if timely filed. Independent provision and the communication, even if timely filed. Independent provision and the communication, even if timely filed. Independent provision and the communication, even if timely filed. Independent provision and the communication, even if timely filed. Independent provision and the communication			<b>#</b> .	
Examiner Charles A. Marmor, II  3736		Application No.	Applicant(s)	
Charles A. Marmor, II 3736	Office Actions Occur	10/612,785	STEPHENS ET AL.	
The MALLING DATE of this communication appears on the cover sheet with the correspondence address — Period for Repty  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ③ MONTH(S) FROM THE MALLING DATE OF THIS COMMUNICATION.  E beaselos of time may be available under the provinces of J CFR 1.136(a). In ne event, however, may a reply be timely liked after SX (b) MONTHS from the misling date of this communication. Set (b) (MONTHS from the mating date of this communication. Set	Office Action Summary	Examiner	Art Unit	
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of liven may be available under the provisions of 37 CFR 1.35(s). In ne event, however, may a reply be timely filed  - Expensions of liven may be available under the provisions of 37 CFR 1.35(s). In ne event, however, may a reply be timely filed  - Expensions of liven may be available under the provisions of 37 CFR 1.35(s). In ne event, however, may a reply be timely filed  - Expensions of liven may be available under the provisions of 37 CFR 1.35(s). However, may a reply be timely filed  - Expensions of liven may be available under the provisions of 37 CFR 1.35(s). However, may a reply be timely filed.  - Expensions of the provision of the provision of the statutory minimum of thinty (30) days will be considered timely.  - Expensions of the provision of the provision of the provision of the statutory may be available of the communication, even if firmely filed, may reduce any readed patent torm adjustment. See 37 CFR 1.704(s).  - Status  - This action is FINAL.  - 2b) This action is non-final.  - 3  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Experte Quayle, 1935 C.D. 11, 453 O.G. 213.  - Disposition of Claims  - 4) Claim(s) 14-24 is/are placed.  - 4) Claim(s) 14-24 is/are placed.  - 5  Claim(s) 14-24 is/are rejected.  - 7) Claim(s) is/are allowed.  - 6  Claim(s) 14-24 is/are rejected.  - 7) Claim(s) is/are objected to.  - 8) Claim(s) 3-25 is/are placed.  - 8) The specification is objected to by the Examiner.  - 8) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  - 8) Application Papers  - 9  The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  - 8) Application provided the provided provided to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  - 8) Replacement drawing sheel(s) including the correction is require				
THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 3 CFR 1.13(6). In no event, however, may a reply be timely filed after SIX (5) MONTHS from the mailing date of this communication.  I this period ravely septicinal double under the provision of 10% days, a reply with the saturacy minimum of thish, (20) days will be considered filently.  Failure for reply within the set or extended period for reply will, by a tenture, and a period will varie fix (5) MONTHS from the mailing date of this communication.  Failure to reply within the set or extended period for reply will, by a tenture, and period will varie fix (5) MONTHS from the mailing date of this communication, even if timely filed, may reduce any search plant from a diplatment. See 37 CFR 1.704(6).  Status  1) Responsive to communication(s) filed on				
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#### **DETAILED ACTION**

1. The Preliminary Amendment filed July 2, 2003 is acknowledged. Claims 1-13 have been canceled. New claims 14-24 have been added. Claims 14-24 are pending.

## Specification

- 2. The disclosure is objected to because of the following informalities: In the first paragraph of the specification, added in the Preliminary Amendment filed July 2, 2003, the current status of the parent application should be provided. Appropriate correction is required.
- 3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 14-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al. ('469). Burbank et al. teach a method and apparatus for automated biopsy and collection of soft tissue. The apparatus includes a rotatable elongated piercing element 44 and an elongated cutter

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68 disposed within the piercing element. The piercing element has a sharpened distal end 45 and a port 46 proximal thereto for receiving a tissue mass. The cutter is adapted to translate and rotate within the elongated piercing element to harvest a tissue mass received within the port of the piercing element. The elognated piercing element is operatively associated with the cutter. Rotation of the piercing element is operatively associated with rotation of the cutter through the control unit 118. Rotation of the cutter and rotation of the piercing element may also be "associated" by rotating the housing 14 of the apparatus a predetermined number of degrees. The control unit 118 controls rotation of the piercing element and a device 48,52 for automatically rotating the piercing element. Multiple samples can be obtained about a longitudinal axis of the piercing element without manually rotating the piercing element. A portion 48 of the device for automatically rotating the piercing element is at least partially disposed on the cutter when apparatus is assembled and the cutter extends through the proximal portion of the piercing element. In operation, the biopsy probe is selectively rotated about a longitudinal axis thereof by rotating the piercing element a predetermined number of degrees in association with motion of the cutter in that the piercing element is rotated after the cutter is rotated and translated to sever a tissue sample received within the port.

### **Double Patenting**

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 14-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-9 and 13 of U.S. Patent No. 6,620,111. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of the patent. The limitations of claims 14, 16, 18 and 19 of the instant application are recited in claims 1 and 7 of the patent. The limitations of claims 15 and 20 of the instant application are recited in claims 3 and 9 of the patent. The limitations of claims 17 of the instant application are recited in claims 2 and 8 of the patent. The limitations of claims 21-24 of the instant application are recited in claims 13 of the patent. Since the broader claims of the instant application are anticipated by the claims of the patent, the claims are not patentably distinct.

#### Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Terwilliger ('970) teaches a biopsy needle set including an outer cannula and an inner cannula, where the cannulas are rotatable relative to one another. Evans ('229) teaches a rotating needle biopsy device. Burbank et al. ('727) teach a tissue acquisition system and method of use thereof.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II Primary Examiner

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June 14, 2004